UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,681	09/30/2004	Robert T. Striker	960296.00543	5680

27114 7590 11/12/2008

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/711,681	STRIKER ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7,8,14,16,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-13,15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 7, 8, 14 , 16, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 15, 2008.

2. Applicant's election with traverse of compound of formula I as the compound species, and hepatitis C as the disease species in the reply filed on July 15, 2008 is acknowledged. The traversal is on the ground(s) that I) compounds of formula I and II are structurally similar; and II) that hepatitis C and BVDV are closely related virus. The argument I are partially persuasive regarding the structural similarity compound I and II, but are not persuasive regarding the compounds recited in claims 7, 8, 14, 16, 19 and 20 which read on a derivative of the compound I or II with a carbohydrate moiety or a targeting agent. Such a compound is in different class/subclass (514/45, or depending on the targeting agent), and are structurally distinct from compound I or II. Therefore, the species election requirements among compounds I and II and their metabolite is herein withdrawn in view of applicant's traverse. The argument II is not found persuasive because hepatitis C and BVDV are two distinct viruses as they infect different mammals.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claims 9, 10, 17-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent

form, or rewrite the claim(s) in independent form. Claim 9 and 10, depending on claim 1, recite metabolite of compound (I) or (II). Note metabolite of compound (I) or (II) is not within the scope of claim 1. Similarly, Claim 17 and 18, depending on claim 11, recite metabolite of compound (I) or (II). Note metabolite of compound (I) or (II) is not within the scope of claim 11.

Claim Rejections 35 U.S.C. 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9, 10, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 9 and 17 recites the limitation "a derivative" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims Rejections 35 U.S.C. 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 9, 10, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Korant (WO00/21565).

9. Calims 9, 10, 17 and 18 read on administering to hepatitis C patient a effective amount of 6-mercaptopurine. The effective amounts herein are defined as about 0.01 mg/kg to about 50 mg/kg of body weight. See [para 65] of the specification.

10. Korant teaches a method of treating hepatitis C infection comprising administering to the patient a cytotoxic agent, such as 6-mercaptopurine. See, particularly, page 4, lines 15-24, page 6, line 17. Korant teaches a preferred dosage range of 0.1 mg to 30 mg/kg of body weight. See, page 17, lines 3-12.

11. Claims 9, 10, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Stuyver (US 2005/0049220).

12. Stuyver teaches a method of treatment of hepatitis C infection comprising administering to the patient an antimetabolite, such as 6-mercaptopurine, or azathioprine. See, particularly, the abstract, paragraphs [0100]. The amount of antimetabolite may be in the range of 100 mg to 1500 mg per day [0071].

Claim Rejections 35 U.S.C. 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-6, 9-13, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korant (WO00/21565), in view of Gunnarsdottir et al. (J. Pharmal Exp. Therapeutics, IDS) .

15. Korant teaches a method of treating hepatitis C infection comprising administering to the patient a cytotoxic agent, such as 6-mercaptopurine. See, particularly, page 4, lines 15-24, page 6, line 17. Korant teaches a preferred dosage range of 0.1 mg to 30 mg/kg of body weight. See, page 17, lines 3-12.

16. Korant does not teach expressly an example for employment of 6-mercaptopurine for treating hepatitis C infection, or the employment of the particular prodrug of 6-mercaptopurine.

17. However, Gunnarsdottir et al. disclose that the AVTG (the compound I) is a known prodrug of 6-mercaptopurine, with less bone marrow toxicity. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ 6-mercaptopurine, or its prodrugs, such as compound I for treatment of hepatitis C.

A person of ordinary skill in the art would have been motivated to employ 6-mercaptopurine, or its prodrugs, such as compound I for treatment of hepatitis C because 6-mercaptopurine is known to be useful for treatment of hepatitis C and a known prodrug would have reasonably been expected to be similarly useful as the drug itself. One of ordinary skill in the art would have been further motivated to use compound I because of its less bone marrow toxicity. Further, a method known to be useful for treatment of hepatitis C infection would have been expected to be useful for treatment of any patient with Hepatitis C, including the host of a

liver transplant patient. Claims 5 and 6 merely recite a biological passway of the prodrug and do not carry any limitation to any step of claimed method.

18. Claims 1-6, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuyver (US 2005/0049220), in view of Gunnarsdottir et al. (J. Pharmal Exp. Therapeutics, IDS)

.

19. Stuyver teaches a method of treatment of hepatitis C infection comprising administering to the patient an antimetabolite, such as 6-mercaptopurine, or azathioprine. See, particularly, the abstract, paragraphs [0100]. The amount of antimetabolite may be in the range of 100 mg to 1500 mg per day [0071].

20. Stuyver does not teach expressly the employment of the particular prodrug of 6-mercaptopurine.

21. However, Gunnarsdottir et al. disclose that the AVTG (the compound I) is a known prodrug of 6-mercaptopurine, with less bone marrow toxicity. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ a prodrugs of 6-mercaptopurine, such as compound I for treatment of hepatitis C.

A person of ordinary skill in the art would have been motivated to employ a prodrugs of 6-mercaptopurine, such as compound I for treatment of hepatitis C because a known prodrug would have reasonably been expected to be similarly useful as the drug itself. One of ordinary skill in the art would have been further motivated to use compound I because of its less bone marrow toxicity. Further, a method known to be useful for treatment of hepatitis C infection would have been expected to be useful for treatment of any patient with Hepatitis C, including

the host of a liver transplant patient. Claims 5 and 6 merely recite a biological passway of the prodrug and do not carry any limitation to any step of claimed method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617